SYNNESTVEDT & LECHNER LLP

In re Application of Shian-Jiun Shih, et al.

Application No. 09/763,210

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Amendments to the Claims

What is claimed is:

1. (Original) A composition comprising a recombinant adenovirus vector and a concentration of human serum albumin (HSA) effective to stabilize the adenovirus vector at a temperature above the freezing point of water or to enhance a titer of the adenovirus vector compared to a titer in the absence of HSA, or both, in an aqueous buffer.

- 2. (Original) The composition of claim 1, wherein the concentration of HSA is from about 0.01% to about 25% (w/v).
- 3. (Original) The composition of claim 2, wherein the concentration of HSA is from about 0.1% to about 15%.
- 4. (Original) The composition of claim 3, wherein the concentration of HSA is from about 1% to about 10%.
- 5. (Original) The composition of claim 4, wherein the concentration of HSA is about 5%.
- 6. (Currently amended) The composition of claim 1, wherein the pH of said composition is greater than or equal to 5.0 and less than or equal to 9.0.
- 7. (Currently amended) The composition of claim 6, wherein the pH of said composition is greater than 7.5.

- 8. (Currently amended) The composition of claim 7, wherein the pH of said composition is greater than 8.0.
- 9. (Currently amended) The composition of claim 8, wherein the pH of said composition is 8.2.
- 10. (Currently amended) The composition of claim 8, wherein the pH of said composition is 8.4.
- 11. (Currently amended) The composition of claim 4, wherein the pH of said composition is greater than 8.0.
- 12. (Currently amended) The composition of claim 5, wherein the pH of said composition is 8.2.
- 13. (Currently amended) The composition of claim 5, wherein the pH of said composition is 8.4.
- 14. (Original) The composition of claim 1, wherein the buffer is a Tris-HCl buffer.
- 15. (Original) The composition of claim 11, wherein the buffer is a Tris-HCl buffer.
- 16. (Original) The composition of claim 12, wherein the buffer is a Tris-HCl buffer.

- 17. (Original) The composition of claim 13, wherein the buffer is a Tris-HCl buffer.
- 18. (Original) The composition of claim 1, further comprising about 5% sucrose, about 2.0 mM MgCl₂ and about 150 mM NaCl.
- 19. (Original) The composition of claim 15, further comprising about 5% sucrose, about 2.0 mM MgCl₂ and about 150 mM NaCl.
- 20. (Original) The composition of claim 16, further comprising about 5% sucrose, about 2.0 mM MgCl₂ and 150 mM NaCl.
- 21. (Original) The composition of claim 17, further comprising about 5% sucrose, about 2.0 mM MgCl₂ and 150 mM NaCl.
- 22. (Original) The composition of claim 1, wherein the recombinant adenovirus expresses a heterologous protein.
- 23. (Original) The composition of claim 22, wherein the heterologous protein is p53.
- 24. (Original) The composition of claim 22, wherein the heterologous protein is HSV-TK.
- 25. (Currently amended) A method for preparing a stabilized recombinant adenovirus formulation comprising preparing an admixture of a recombinant adenovirus comprising suspending a recombinant adenovirus in an aqueous buffer

comprising a concentration of human serum albumin (HSA) effective to stabilize the adenovirus vector at a temperature above the freezing point of water, or enhance a titer of the adenovirus vector compared to a titer in the absence of HSA.

- 26. (Original) The method according to claim 25, wherein the temperature is greater than or equal to 4°C and less than 37°C.
- 27. (Original) The method according to claim 25, wherein the temperature is greater than or equal to 20°C.
- 28. (Original) The method according to claim 26, wherein the concentration of HSA is 5%.
- 29. (Original) The method according to claim 26, wherein the pH of the admixture is greater than 8.0.
- 30. (Original) The method according to claim 26, wherein the pH of the admixture is 8.2.
- 31. (Original) The method according to claim 26, wherein the pH of the admixture is 8.4.
- 32. (Withdrawn) A method for stabilizing an adenovirus vector at about 20°C, which comprises preparing an admixture of the adenovirus vector in an aqueous composition of Dulbecco's phosphate buffered saline, from about 5% to 15% glycerol, from about 0.25 to 2.0 mM CaCl₂ and from about 0.1 to 1.0 mM MgCl₂.

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33. (Withdrawn) The method according to claim 32, wherein the concentration of glycerol is about 10%, the concentration of CaCl₂, is about 1.0 mM, and the concentration of MgCl₂ is about 0.5 mM.